Workshop on Behavior-Based Donor Deferrals in the NAT Era: Introduction

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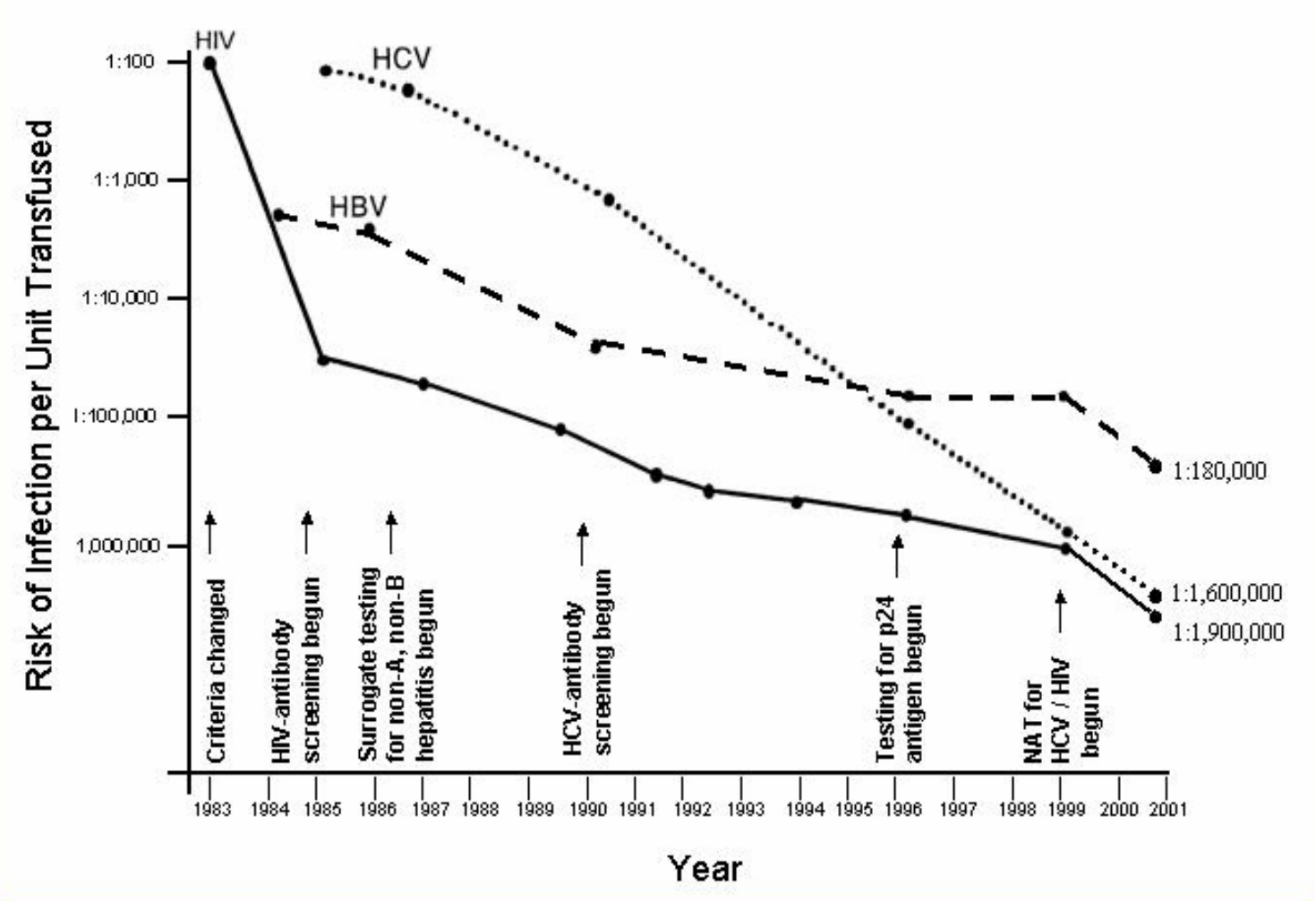
FIVE LAYERS OF BLOOD SAFETY

FDA's approach is to optimize each safety layer:

1. Donor screening and deferral based on geographic, behavioral and medical risk factors (donor education, self deferral, donor interview)
2. Laboratory testing and deferral (HIV-1, HIV-2, HBV, HCV, HTLV-I, HTLV-II, WNV, syphilis)
3. Deferral registries to prevent use of blood from deferred donors
4. Quarantine controls to prevent unit release pending verification of donor suitability
5. Investigation and correction of deviations

New Test Implementation and Declining Risk of Viral Infections from Transfusion



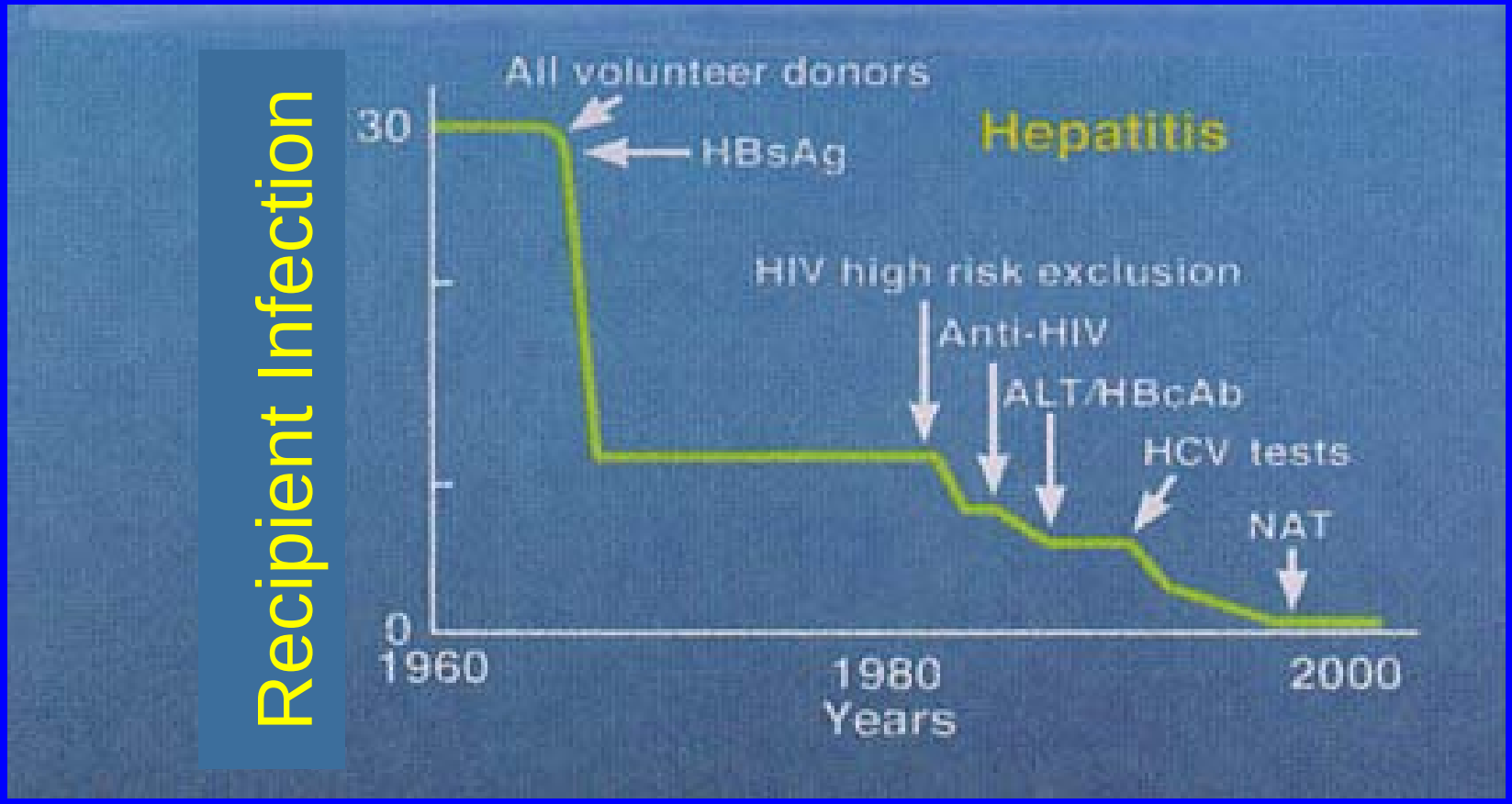
Risk of Transfusion Transmission of Selected Agents in the USA*

Infectious units per year entering the blood supply*

	Risk per Million Donations	Number of Contaminated Blood Components
HBV	3.6	85
HTLV	1.5	36
HIV	0.5	12
HCV	0.5	12

* Based on 14 million collections yielding 23 million components

Relative Benefits of Donor Screening and Testing for Viral Hepatitis



Evolution of Testing and Deferral

What happens when an emerging pathogen threatens the safety of the blood supply?

1. We introduce deferral criteria based on epidemiologically determined risk factors (medical, geographic or behavior-related exposures) as an initial safety measure
2. Where feasible, tests are developed, but deferral is maintained as an overlapping safeguard
3. Test sensitivity and specificity generally improve. However, risk-based deferrals are usually retained as an overlapping safeguard, especially when data are lacking on the relative safety contribution of risk-based vs. test-based deferrals

Evolution of Testing and Deferral

4. Over time, the expansion of risk-based and test-based deferrals has enhanced blood safety, but has added to complexity.

4. As the number of risk-based deferral criteria has increased, it has been asked whether the blood donor questionnaire is as effective as it should be, and whether simplification would enhance its value.

5. Additionally, the question has arisen whether testing has become so effective that some risk-based deferrals no longer provide a significant added safety value.

Social Issues in Donor Selection

- FDA is aware that some current donor selection criteria have been perceived by some individuals as possibly based on prejudice or on past needs rather than current science.

- We hope that this forum will clarify the rationale for current deferrals and provide an opportunity for scientific input and discussion into donor policies.

Social Issues in Donor Selection

- We recognize that the blood system depends on the trust, generosity and good will of donors, and we very much appreciate the altruism and intended social contribution of all who seek to donate.

- While we consider donors' perspectives very carefully and seriously, (indeed this is part of the reason for today's workshop) FDA's primary responsibility is to the safety of the blood supply and of those who receive blood and blood products.

Primary Goals of the Workshop

- Public discussion of the scientific basis for use of behavior-based donor deferral criteria to prevent transfusion transmitted infectious diseases (TTD's), and
- Consideration whether the blood safety advancements from introduction of nucleic acid based tests (NAT), or other measures, would permit changes to these deferrals without compromise to blood safety

STRUCTURE OF THE WORKSHOP

I. Review of current behavior-based deferrals
- FDA's policies for blood and HCT/P donors
- Effectiveness of donor screening procedures
- Deferral policies in Europe
- Social dimensions of the issue
- Association of behaviors with TTD risks

- Discussion Question:
  - What behaviors are associated with risks of TTD and how do these risks compare amongst cohort groups with these behaviors?

STRUCTURE OF THE WORKSHOP

II. Assessing the risk of TTD's
  - Current estimates for risk of TTD's
  - Inventory errors as a source of risk
  - Risk estimates for certain modified deferrals
  - Value of donor questionnaires
- Discussion Question:
  - How do behavior-based deferrals contribute to blood safety when donors additionally are tested by NAT?

STRUCTURE OF THE WORKSHOP

III. Potential alternatives for blood donor screening and testing
  - Review of alternatives
  - Behavioral risks in relation to EID's
- Issues for Discussion:
  - Implications of the quantitative risk models
  - Needs for additional scientific data

Workshop on Behavior-Based Donor Deferrals in the NAT Era

We value everyone's contribution to this workshop!